

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

RAMY SHAKER, TRACY
KNIERIM, LISA BARTA, and
CHERYL WELLNITZ, individually
and on behalf of a class of similarly
situated individuals,

Plaintiffs,
v.

CHAMPION PETFOODS USA,
INC. and CHAMPION PETFOODS
LP,

Defendants.

Case No. 2:18-cv-13603-LJM-DRG

Honorable Laurie J. Michelson

Magistrate Judge David R. Grand

**PLAINTIFFS' REVISED MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' REVISED MOTION TO EXCLUDE PLAINTIFFS'
EXPERT SEAN CALLAN'S PENTOBARBITAL OPINIONS**

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COUNTER-STATEMENT OF ISSUES PRESENTED

- I. Whether Dr. Sean Callan's opinions on the likelihood of the presence of pentobarbital in Champion's finished pet food are reliable and relevant to the facts in dispute?

Plaintiffs' Answer: YES

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Fed. R. Evid. 702

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In re Scrap Metal Antitrust Litig., 527 F.3d 517 (6th Cir. 2008)

Plaintiffs oppose CPF's Revised Motion to Exclude the Opinions and Testimony of Plaintiffs' Proffered Expert Sean Callan ("Motion").¹ This Court should respectfully deny CPF's Motion in its entirety for the reasons set forth below.

I. INTRODUCTION

CPF's arguments for excluding Dr. Callan's opinions—that his testimony is irrelevant, baseless, and speculative and that his methodologies are flawed—should be rejected. The criticisms in the Motion, at best, go only to the weight of Dr. Callan's opinions. Thus, it is up to a jury to decide the weight to give Dr. Callan's opinions. Dr. Callan is a highly qualified professional whose testimony in this action meets the relevance and reliability requirements of Rule 702 of the Federal Rules of Evidence ("Rule 702") and *Daubert v. Merrell DOW Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). Based on his extensive experience and knowledge, and his review and analysis of relevant documentation and materials, Dr. Callan produced a report opining on: the presence of pentobarbital in certain raw materials used in creating the Dog Food;² the likely presence of pentobarbital at some level in the Dog Food; and the insufficiency of the random sampling performed by CPF to determine the risk of pentobarbital in the Dog Food. Dr. Callan's expert opinions are based on

¹ "CPF" refers collectively to defendants Champion Petfoods USA, Inc. and Champion Petfoods LP.

² For purposes of this memorandum and Dr. Callan's report, the term "Dog Food" is limited to Orijen Regional Red.

sufficient data and sound methodology, guided by his qualifications in the relevant fields, and are, as a result, helpful for a jury to understand the evidence and analysis related to the pentobarbital allegations in the present case. For these reasons and as discussed further below, CPF's Motion should be denied.

II. LEGAL STANDARD

“Rule 702 [] controls the admissibility of all types of expert testimony.” *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 176 (6th Cir. 2009). “According to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), a district court's task in assessing evidence proffered under Rule 702 is to determine whether the evidence ‘both rests on a reliable foundation and is relevant to the task at hand.’” *Id.*³ “‘If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.’” *Id.* (quoting Fed. R. Evid. 702).

“In the Sixth Circuit, the threshold for indicia of reliability in a *Daubert* motion is a liberal one.” *Innovation Ventures, L.L.C. v. Custom Nutrition Lab's, L.L.C.*, 520 F. Supp. 3d 872, 880 (E.D. Mich. 2021). “Rule 702 does not require unstinting perfection in presenting test results.” *United States v. Gissantaner*, 990

³ Here, as throughout, all emphasis is deemed added and citations and footnotes are deemed omitted unless otherwise noted.

F.3d 457, 469 (6th Cir. 2021). “In other words, they need not convince the Court that the methodology employed by their expert is flawless in order to have his expert testimony admitted.” *Burke ex rel. Burke v. U-Haul Int’l, Inc.*, No. 03-cv-32, 2006 WL 3043421, at *6 (W.D. Ky. Oct. 20, 2006).

“Daubert and Rule 702 require only that the expert testimony be derived from inferences based on a scientific method and that those inferences be derived from the facts on the case at hand ... not that they know the answers to all the questions a case presents...”

Nemir v. Mitsubishi Motor Sales of Am., Inc., 6 F. App’x 266, 275 (6th Cir. 2001).

“One key consideration is “whether the reasoning or methodology underlying the testimony is scientifically valid.” The inquiry is “a flexible one,” and “the focus ... must be solely on principles and methodology, not on the conclusions they generate.”“ *Jacobs v. Alam*, No. 15-cv-10516, 2019 WL 6003132, at *4 (E.D. Mich. Nov. 13, 2019), *reconsideration denied*, 2019 WL 7172006 (E.D. Mich. Dec. 23, 2019). “[E]xclusion remains the exception, and “[v]igorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”“ *Nationwide Mut. Fire Ins. Co. v. Black & Decker (U.S.), Inc.*, No. 13-cv-14312, 2015 WL 4243281, at *5 (E.D. Mich. July 13, 2015) (quoting *Daubert*, 509 U.S. at 596). The Court’s role is to “act as a gatekeeper and ensure that all expert testimony is not only relevant, but reliable. Not only must such testimony be based on reliable principles and methods, but it must also assist the trier of fact.” *Cervo v. Am.*

Steamship Co., No. 02-cv-70864, 2003 WL 25676101, at *5 (E.D. Mich. July 1, 2003) (citing *Nelson v. Tenn. Gas Pipeline*, 243 F.3d 244, 250 (6th Cir.2001)). “The task for the district court in deciding whether an expert’s opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation.” *In re Scrap Metal Antitrust Litig.* (“*Scrap Metal*”), 527 F.3d 517, 529-30 (6th Cir. 2008). “*Daubert* quite clearly forbids trial judges to assess the validity or strength of an expert’s scientific conclusions, which is a matter for the jury.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 154 (1997) (Stevens, J. concurring in part).

“Rule 702 guides the trial court by providing general standards to assess reliability” *Scrap Metal*, 527 F.3d at 529. Relevant questions include “whether the testimony is based upon ‘sufficient facts or data,’ whether the testimony is the ‘product of reliable principles and methods,’ and whether the expert ‘has applied the principles and methods reliably to the facts of the case.’” *Id.* (quoting Fed. R. Evid. 702). “The trial court’s objective ‘is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Nat’l Parks Conservation Ass’n, Inc. v. Tenn. Valley Auth.*, No. 01-cv-71, 2008 WL 4059826, at *2 (E.D. Tenn. Aug. 28, 2008) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). The Court should

“consider[] a proposed expert’s ‘full range of practical experience as well as academic or technical training when determining whether that expert is qualified to render an opinion in a given area.’” *Penn. Lumbermens Mut. Ins. Co. v. Precision Lawn Irrigation Inc.*, No. 18-cv-13261, 2020 WL 8673131, at *12 (E.D. Mich. Nov. 25, 2020). Thus, “an expert need not have direct experience with the product at issue,” *id.*, nor must his testimony “be based on firsthand knowledge,” *Cervo*, 2003 WL 25676101, at *5. Instead, it must only “ha[ve] a reliable basis in the knowledge and experience of the [expert’s] discipline.” *Id.*; *see also Penn. Lumbermens Mut. Ins. Co.*, 2020 WL 8673131, at *12.

III. ARGUMENT

A. Dr. Callan Is Qualified to Render His Opinions Regarding Pentobarbital Being “Likely Present” at “Some Level.”

CPF’s efforts to discredit Dr. Callan’s opinions regarding the likely presence of pentobarbital in the Dog Food as baseless, speculative, and irrelevant are unpersuasive and should be rejected. Dr. Callan’s pentobarbital opinions are based on his extensive relevant qualifications, reliable methodology, and proper analysis of reliable evidence from CPF and the U.S. Food and Drug Administration (“FDA”).

Experts are not required to have specialized knowledge with the products at issue. *Penn. Lumbermens Mut. Ins. Co.*, 2020 WL 8673131, at *12. Instead, courts should “consider[] a proposed expert’s ‘full range of practical experience as well as academic or technical training when determining whether that expert is qualified to

render an opinion in a given area.” *Id.* Dr. Callan’s extensive qualifications easily meet this criterion. He specializes in “statistics, research methodology, toxicology, and biochemistry.” (ECF No. 106-2, PageID.14443 ¶1.) He also has a doctorate in psychology and has researched and published seven peer-reviewed articles on topics such as lead and cadmium contamination in infant formulas and the effects of exposure to various toxic substances. (*Id.*, PageID.14451-52.) Dr. Callan is a sought-after speaker on the subject of toxin exposures and has “lectured on the topics of analytical design and data analysis.” (*Id.*, PageID.14444 ¶4(d), 14453-54.) He also teaches graduate level statistics courses and introductory biopsychology and psychopharmacology courses. (*Id.*, PageID.14456-57.) Perhaps most significantly, Dr. Callan is currently Chief Operating Officer and a past Senior Vice President and Director of Research, Development, and Quality of Ellipse Analytics, an analytical chemistry lab that tests samples of food and other consumer goods for industrial contaminants and environmental toxins, and he has previously worked with a company to undertake a risk assessment regarding contamination of raw materials getting into a finished product. (*Id.*, PageID.14443-44, 14451-60); Ex. 3, *Daubert* Hearing (Part I) in *Zarinebaf v. Champion Petfoods USA Inc.*, September 22, 2021, at 159:16-160:18. These qualifications and expertise in the actual area he is testifying about (i.e., toxicology) reflects a significant part of his life’s work.

Second, Dr. Callan's opinions are based on his thorough review of transcripts of depositions taken in this matter, relevant documents produced by CPF, relevant filings, and relevant FDA reports and other documents related to the undisputed pentobarbital contamination of the Dog Food. (*Id.*, PageID.14444-46.) Dr. Callan's review and analysis of evidence included CPF records that showed JBS USA Holdings, Inc. and its rendering facility MOPAC, located in Eastern Pennsylvania (collectively, "JBS") supplied at least two lots of tallow that were contaminated with pentobarbital and later used in the production of the Dog Food. (ECF No. 106-4, PageID.14472-73 (8:11-14, 8:23-9:3).)

The pentobarbital-related evidence that Dr. Callan carefully and thoroughly analyzed is undeniably reliable, and his pentobarbital opinions based on such reliable evidence are informed by sound methodologies. More specifically, the relevant documents that Dr. Callan examined included documents supporting the fact that pentobarbital was indeed present in two lots of tallow shipped to CPF. For example, Dr. Callan reviewed documents related to FDA pentobarbital testing from 2002, the FDA's Establishment Inspection Report at CPF, as well as relevant correspondence between CPF and the FDA. Dr. Callan's expert opinion includes the fact that the pentobarbital allowed to contaminate the Dog Food would not be eliminated by the manufacturing process. (ECF No. 106-2, PageID.14447-50.) In other words, once the pentobarbital was introduced through the ingredients used to manufacture the

food, some level or amount of pentobarbital would ultimately remain in the finished kibble. *Id.* Dr. Callan testified:

In the previous parts of the report, we discuss how pentobarbital was present in a raw material made by JBS, purchased by Champion. That raw material was, in turn, used to create a finished product. We know from the work the FDA has done that raw material—the pentobarbital contained within that raw material is not destroyed in entirety during the manufacturing process. So the logic there is it is likely that Champion pet food, made with contaminated starting material, contains some amount of pentobarbital.

(ECF No. 106-4, PageID.14534-35 (70:18-71:3).)

Relying at least in part on information from CPF and the FDA, Dr. Callan concluded that pentobarbital was introduced into the Dog Food via the contaminated beef tallow; and that some, if not all, of the pentobarbital then survived the manufacturing process; and the corresponding Dog Food contained some level of pentobarbital. (ECF No. 106-2, PageID.14448-50.) Dr. Callan testified as such:

Q. When you say “some level,” what do you mean?

A: I go into more detail later in the report on this, which I presume we’re going to go to at some point here. But because pentobarbital is present in one of the ingredients and because pentobarbital is not destroyed during the manufacturing process and because that ingredient is being included in the finished product, some amount of that pentobarbital will persist in the finished good.

(ECF No. 106-4, PageID.14476-77 (12:25-13:9); *see also id.*, PageID.14524 (60:18-20) (“What we do know with certainty is that not all of it [the pentobarbital] is destroyed because it has persisted into finished food product, in the FDA’s report.”);

id., PageID.14477 (13:15-19) (“[I]f there is pentobarbital present in a raw material and you put that raw material into another larger group, you may dilute the amount of pentobarbital that’s present, but you don’t remove it. It’s still there.”).)

CPF argues that Dr. Callan’s opinion that the Dog Food contains some level of pentobarbital is “baseless” because he fails to criticize or replicate Texas A&M’s testing. (ECF No. 106, PageID.14423-28.) However, as Dr. Callan’s report and testimony reflect, his opinions and the findings of Texas A&M are not mutually exclusive:

The proper conclusion in the event of a “non-detect” is to conclude just that – that the testing chemist (here Texas A&M laboratory) was unable to detect the analyte. This does *not* mean the analyst is asserting that the analyte was not present at some level. As such, the non-detect findings of the Texas A&M laboratory do not contradict [Dr. Callan’s] logic.

(ECF No. 106-2, PageID.14449 ¶6(d)(1)); *see also* Ex. 3 at 167:11-19 (“Below the limit of detection that the lab establishes, all that the analytical chemist can say is that they are unable to reliably see it, not that it’s not there.... [I]f it [pentobarbital] were present at one part per billion, the chemist would return non-detect. That doesn’t mean there’s no pentobarbital present, only that they couldn’t see it.”). Dr. Callan’s opinion is that the small sample of the Dog Food tested contains some level of pentobarbital, which includes amounts below 2 parts per billion (“ppb”). (ECF No. 106-2, PageID.14448-50.) Dr. Callan specifically testified to this point:

Q: And that logical explanation, I take it, is that the pentobarbital in the ingredient, incoming ingredient, beef tallow, was diluted to such an extent that if it's present at all, it's below 2 parts per billion?

A: That is the argument, yes.

(ECF No. 106-4, PageID.14535 (71:14-19).)

CPF's own purported expert, Dr. Robert Poppenga, reached the same conclusion, confirming that a "non-detect" finding at Texas A&M does not preclude the possibility that the small sample of the Dog Food tested for pentobarbital could contain pentobarbital below 2 ppb. His specific deposition testimony on this point is as follows:

Q: And so let's say of those 11 samples that were tested by Texas A&M, if they contain 1.5 parts per billion of pentobarbital, would Texas A&M's testing pick that up?

A: No. Their reporting limit, their limit of detection, was two parts per billion.

Q: And same if one of them had 1.75 parts per billion?

A: Correct.

Q: And 1.9 parts per billion?

A: In theory, no, because it's two parts per billion or greater.

Ex. 1, Dep. of Dr. Robert Poppenga, August 26, 2019, at 29:8-19.

Dr. Callan's underlying calculations and resulting opinions with regard to the pentobarbital will be helpful for a jury to understand that some amount of pentobarbital was present in the Dog Food at issue, despite Texas A&M's "non-

detect” testing result, which only precludes the possibility that the few samples tested did not have pentobarbital in excess of 2 ppb. Dr. Callan’s helpful opinions are based on a methodical and careful analysis of relevant and reliable authoritative documents, following the information and data obtained from the evidence in a step-by-step process, to reach his opinions.

Dr. Callan’s expert report indeed reveals sound methodology applied to the facts of this case to reach sound, reliable, and helpful expert opinions. Dr. Callan “need not testify to what is ‘known to a certainty’ but must only state ‘an inference or assertion ... derived by the scientific method.’” *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) (quoting *Daubert*, 509 U.S. at 590). Thus, his opinion that CPF’s Dog Food “would contain some amount of pentobarbital” is permissible. Whether that opinion is credible “should be left for the finder of fact.” *Id.* at 391.

CPF also argues for exclusion of Dr. Callan’s expert opinions because Dr. Callan only observed, but did not do, the testing leading to his opinions. (ECF No. 106, PageID.14425-27.) As the Federal Rules of Evidence and case law from this District and the Sixth Circuit make clear, Dr. Callan is not required to conduct his own testing and can instead rely upon sufficient and reliable data to come to his opinion which, as discussed above, is exactly what occurred. *See Fed. R. Evid.* 703 (“An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.”). “There is no requirement that an expert’s

theories must actually be tested in order to satisfy the *Daubert* inquiry.” *Anderson v. Ridge Tool Co.*, No. 06-cv-116, 2008 WL 3849923, at *5 (E.D. Ky. Aug. 14, 2008). “Experts are permitted a wide latitude in their opinions, including those not based on firsthand knowledge, so long as ‘the expert’s opinion [has] a reliable basis in the knowledge and experience of the discipline.’” *Jahn*, 233 F.3d at 388 (quoting *Daubert*, 509 U.S. at 592). Here, CPF does not challenge the underlying data, and Dr. Callan did not merely pull the information he relied on “out of thin air” or based his opinions on “‘assumptions’ or ‘guesses.’” *Scrap Metal*, 527 F.3d at 530-31.

“The Federal Rules of Evidence relax the hearsay rule on opinion testimony for experts and allows an expert to base an opinion on ‘facts or data in the case that the expert has been made aware of,’ rather than just what the witness has ‘personally observed.’” *Innovation Ventures*, 520 F. Supp. 3d at 892 (quoting Fed. R. Evid. 703). Dr. Callan’s expert opinions are “based upon facts in the record,” such as information from the FDA, the Texas A&M lab, and testimony from JBS employees, among other evidence. *Scrap Metal*, 527 F.3d at 530. And Dr. Callan has “sufficiently established how the underlying data supports [Dr. Callan]’s expert report.” *Innovation Ventures*, 520 F. Supp. 3d at 890. CPF’s “challenges merely [go] to the accuracy of the conclusions, not to the reliability of the testimony.” *Scrap Metal*, 527 F.3d at 530. “The question of whether [Dr. Callan’s] opinion is accurate in light of his use of [this] data goes to the weight of the evidence, not to its

admissibility,” and the jury should and must be tasked with making those determinations.” *Id.* at 531-32.

Moreover, despite CPF’s suggestions to the contrary, Dr. Callan’s testimony that he understands that the FDA considers a product with “detectable” levels of pentobarbital to be adulterated is not a concession that the Dog Food is unadulterated. (ECF No. 106-4, PageID.14567-68 (103:18-104:21).) CPF misconstrues Plaintiffs’ allegations, which rest solely on whether *any* amount of pentobarbital was present in the Dog Food. CPF does not dispute Dr. Callan’s correct opinion that “the failure to detect pentobarbital in the finished product is the result of serial dilution of the pentobarbital as raw materials are blended into finished goods, not the absence of the compound in the finished product.” (ECF No. 106-2, PageID.14448-50 ¶6(d)); *see also* Ex. 3 at 168:23-169:14 (It was inappropriate for CPF to state the results as “non-detect” because Texas A&M’s “instrumentation, their methodology, was not sensitive enough for the purpose in question.... It was inappropriate to conclude an all-clear. It’s what statisticians refer to as a type II or beta error [a false negative].”). In other words, “non-detection” of pentobarbital does not mean a categorical conclusion that no pentobarbital is present. As mentioned above, CPF’s own expert witness, Dr. Poppenga, confirms that “non-detect” does not exclude this possibility. Ex. 1 at 29:8-19. Dr. Callan further elucidates this point as follows:

[A] more plausible conclusion in line with all available information is that the pentobarbital present in the JBS raw material has been diluted below the ability of Texas A&M to detect rather than eliminated during processing. Indeed, based on Champion’s own estimations (provided by Exponent), the inclusion rate for beef tallow in Champion products ranged from 2.89% to 6.07%. This means that a 16 ppb pentobarbital hit (the low point of the two lots of tallow we know Champion purchased from JBS) in tallow would be diluted down to below 1ppb in the finished kibble (0.46ppb) – below the stated LODs of the laboratories performing the testing. This would give the false impression of an “all clear” when in fact the pentobarbital had only been diluted below detection or as discussed below was contained in other parts of the kibble not tested.

(ECF No. 106-2, PageID.14449 ¶6(d)(i).) Thus, as Dr. Callan explains, the Dog Food likely contains some level of pentobarbital.

Dr. Callan’s opinions are helpful for the fact finder as the presence of *any* amount of pentobarbital in the Dog Food is probative of the pentobarbital contamination allegations levied against CPF. CPF’s argument is devoid of any acknowledgement, mention, or reference that pentobarbital can present below a concentration of 2 ppb. While CPF would like to pigeonhole the issue of pentobarbital to this arbitrary threshold, Dr. Callan’s expert opinions are helpful for the jury to understand that pentobarbital can be present even when not “detected” by some limited laboratory testing. And the cases CPF relies on do not advance its arguments. For example, unlike the expert in *Pride v. BIC Corp.*, Dr. Callan relied on “generally accepted scientific principles as applied to the facts of this case.” 218 F.3d 566, 577-78 (6th Cir. 2000). He explains in detail the “difference between

detection and presence,” including why “[t]he proper conclusion in the event of a ‘non-detect’ is to conclude just that—that the testing chemist ... was unable to detect the analyte. This does *not* mean the analyst is asserting that the analyte was not present at some level.” (ECF No. 106-2, PageID.14449 ¶6(d)(i).) Nor is the factual basis for his opinion “nonexistent,” *Jones v. Pramstaller*, 874 F. Supp. 2d 713, 726 (W.D. Mich. 2012), or based on “facts [and] assumptions having nothing at all to do with this case,” *Lake Mich. Contractors, Inc. v. Manitowoc Co.*, 225 F. Supp. 2d 791, 796 (W.D. Mich. 2002). As explained in Section III.B *infra*, he relied on the results of tests of the Dog Food at issue, deposition testimony in this matter, and other evidence related to government investigations of the pentobarbital contamination that led to this lawsuit. His hypothesis is directly supported by that evidence and does not take the leap that the expert in *Abrams v. Nucor Steel Marion, Inc.* attempted. *See* 694 F. App’x 974, 981 (6th Cir. 2017) (finding no support for the opinion that the plaintiffs “‘*w[ould]* suffer [physical] harm’” based on a third party’s air and soil analyses). Rather, he reaches a logical conclusion based on scientific evidence—without forming any opinion on the risk of physical injury to dogs—that “[i]t is likely that [the Dog Food] made from meal and tallow would contain some amount of pentobarbital.” (ECF No. 106-2, PageID.14448 ¶6(d).)

Plaintiffs do not ask the Court to accept Dr. Callan’s testimony “simply ‘because he is an expert.’” (*See* ECF No. 106, PageID.14424 (quoting *Lake Mich.*

Contractors, 225 F. Supp. 2d at 800.) As Dr. Callan's expert opinions would be helpful to a jury, are based on reliable information, sound methodologies, and supported by his expert qualifications, the Court should deny CPF's motion to exclude Dr. Callan's expert opinions regarding pentobarbital.

B. Dr. Callan's Opinions that CPF's Sampling Was "Insufficient to Assess the Actual Risk" Is Based on Dr. Callan's Experience and Expertise and Relies on Sufficient Facts and Data

Dr. Callan is highly qualified to render opinions regarding data sampling and analytics. His expertise includes his background in teaching statistics and research design courses at the both the undergraduate and graduate levels, his prior experience lecturing on these topics, and his day-to-day work at Ellipse Analytics, where Dr. Callan currently serves the Chief Operating Officer. Ex. 3 at 160:17-18. While CPF claims Dr. Callan has no basis for rendering an opinion, in fact, Dr. Callan has direct experience with determining adequate sample sizes for contaminant testing:

Q: Okay. Have you ever done statistical analyses to determine what would be a statistically representative sampling for detecting a toxin in the processing of food?

A: Yes.

Q: Tell me about that.

[Omitted discussion regarding NDA from prior work]

A: Okay. We did some work with a company around the presence of a—of a contaminant of concern, and, you know, it started by identifying the root cause, the—the antecedent material, and then it went into raw material testing to determine the prevalence and frequency. And from there, we developed a plan to perform stratified testing in order to guarantee that the product wasn't present. So the analysis there relied upon knowing several factors. You have to know the frequency with which the contaminant shows up, the concentration with which the contaminant shows up, and the inclusion rate in the finished product, and that helps you then go in and determine, in order to make sure that your product, to a reasonable degree of scientific certainty, is going to be consistently clean, in addition to testing the raw material, which is the key. You have to test the raw material. You can then perform a statistically meaningful and representative sampling of the good as a secondary control.

ECF No. 106-4, PageID.14495-96 (31:6-32:11).

Disregarding these qualifications, CPF argues that Dr. Callan “has no basis for opining that [CPF]’s pentobarbital sampling was insufficient,” and as such should be excluded. (ECF No. 106, PageID.14428.) This is false, and this Court should give due weight to Dr. Callan’s qualifications when deciding CPF’s Motion. *Penn. Lumbermens Mut. Ins. Co.*, 2020 WL 8673131, at *12.

To support its arguments, CPF cherry-picks deposition testimony to give the appearance that Dr. Callan did not know the pertinent details of CPF sampling for pentobarbital. ECF No. 106, PageID.14429-32. However, in fact, Dr. Callan testified that he understood that the CPF sampling process included taking retained samples from storage and using them for testing. (ECF No. 106-4, PageID.14481 (17:5-15).)

He also testified that these retained samples were pulled from various points in CPF's production runs. (*Id.*) CPF nitpicks at Dr. Callan's testimony, focusing on the fact that he did not personally observe the collection of samples and does not know the details of CPF operational procedures (i.e. how long CPF takes to produce a lot of finished Dog Food), while ignoring his familiarity with the sample size of less than one pound. (*Id.*, PageID.14483 (19:7-22).) Given his extensive background and his review of CPF's testing protocol, Dr. Callan is well qualified and well informed to criticize CPF for improperly extrapolating such a small size from 1.7 million pounds of finished Dog Food.

CPF's assertion that Dr. Callan did not quantify parameters for sufficient testing is likewise unfounded and unsupported by Dr. Callan's testimony. (ECF No. 106, PageID.14429-32.) Dr. Callan opined that CPF's sampling size had a margin of error of 20%. (ECF No. 106-2, PageID.14450 ¶6(d)(ii).) Dr. Callan's explained further at his deposition:

Q: Then you talk here about "Testing such a small amount creates a massive 20% margin of error." ...How did you calculate this 20 percent margin of error?

* * *

A: Margin of error calculation, in this instance, is a good proxy for variability. So ... it's a standard formula that you can use in statistics, if you know the total population size, you know the confidence interval that you want to attain, and you know the amount ... of the sample. I mean, it's ... just a straight math formula that tells you it's not.

Q: [W]hat are you relying on for that opinion about 20 percent margin of error?

A: I just said. I know how much kibble there was. I know how much sample they did. I know the confidence interval you want. And then math tells me the margin of error.

(ECF No. 106-4, PageID.14543-44 (79:12-80:5).) Dr. Callan continues, explaining:

A: What that says is, if the goal is to simulate what's actually going on at the population level, here population being defined as the 1.7 million pounds of available ... kibble, that testing 0.26 [pounds of kibble] would result in such a wide degree of error around the true value that it would be difficult to accurately estimate whether you were seeing something real or not."

(*Id.*, PageID.14546 (82:2-9).)

Dr. Callan further opines on how to determine what a sufficient sample size for adequate pentobarbital testing of the Dog Food would be:

Q: That was my next question. What would be an acceptable margin of error under these circumstances?

A: It depends how certain they want to be that they know how much pentobarbital is present in a product. Typically,... in my own personal experience, when conducting analytics, whether it's analytics of ... consumer or human behavior or analytics in this sense, I typically shoot for under 5 percent error.

Q: And that's what you do in the ordinary course of business at Ellipse Analytics?

A: Yeah. Which is to say I want to be 95 percent sure that the true value is within plus or minus 5 percent of what I'm seeing, not plus or minus 20.

(*Id.*, PageID.14547 (83:9-24).) Dr. Callan adds:

Q: Okay. So what should Champion have done?

A: They should have tested a larger amount of sample. And in terms of how much sample, I would have to perform a statistical analysis in order to determine how much.

(*Id.*, PageID.14490 (26:13-17).)

This testimony shows a reality that is much different than the version CPF wants this Court to believe. Dr. Callan's expert report does not attempt to, as CPF argues, "rebut something with nothing." (ECF No. 106, PageID.14432.) Dr. Callan's opinions on the insufficiency of CPF's sampling is based on CPF's miniscule sample size taken from the 1.7 million pounds of kibble. (ECF No. 106-2, PageID.14450.) Dr. Callan expands on this point, noting that such a small sample would create a massive 20 percent margin of error, which is quadruple the margin of error that Dr. Callan would expect to see in an empirically sound and sufficient sample. (*Id.*; ECF No. 106-4, PageID.14547 (83:9-24).) Dr. Callan's suggestion for sufficient testing is straightforward—test more kibble until a 5 percent margin of error is achieved. (ECF No. 106-4, PageID.14547 (83:9-24).)

While Dr. Callan did not opine on the specific amounts of kibble associated with his recommended margin of error, Dr. Callan need not do so to establish that CPF's testing was inadequate. *See* Ex. 3 at 174:21-175:3 (Determining what sample size should have been used was beyond the scope of what Dr. Callan was asked to do—he "didn't need to determine what was appropriate in order to determine that

what they did was insufficient for the conclusion they were trying to reach.”). Furthermore, once again, the cases relied on by CPF are inapposite. They deal with an expert opining on whether the mere presence of a substance caused physical injury, *Baker v. Chevron U.S.A. Inc.*, 533 F. App’x 509, 524 (6th Cir. 2013), and vague personal conjecture that would not assist the jury that damage was “more severe than anything else,” *Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 767 (E.D. Mich. 2010). No such physical injuries are at issue here, as Plaintiffs seek damages based on a price premium and not injury to their pets. (ECF No. 25, PageID.219 ¶¶2-3.) And Dr. Callan has more than a sufficient basis to opine that CPF’s pentobarbital sampling was lacking.

To the extent that CPF disagrees with the factual bases that underpin Dr. Callan’s opinion, it may voice its criticisms through cross-examination and its own expert testimony at trial. CPF’s criticisms go towards the weight, not the admissibility, and this argument is routinely rejected “because it fundamentally confuses the **credibility and accuracy** of [an expert]’s opinion with its **reliability**.” *Scrap Metal*, 527 F.3d at 529. As Dr. Callan’s opinions are based on reliable information, sound methodologies, and his expert qualifications, the Court should not exclude his opinions, which would be helpful to the jury when weighing the evidence presented in this case. *See Jahn*, 233 F.3d at 392-93 (“[E]xperts are just witnesses, and they need not be purveyors of ultimate truth...”).

C. Dr. Callan’s Opinions that Pentobarbital’s Heterogeneous Nature Requires Larger Sample Size for Testing Are Proper

Dr. Callan’s opinions on the heterogeneous nature of beef tallow and the resulting heterogeneous distribution of pentobarbital in the Dog Food is based on reliable information, methodologies, and expertise. In coming to his conclusions, Dr. Callan based his understanding and review on relevant testing data provided from reputable analytical laboratories and documentation from CPF and the FDA. (ECF No. 106-2, PageID.14444-47.)

First, Dr. Callan reviewed documents obtained from the Pennsylvania Department of Agriculture via a Freedom of Information Act (“FOIA”) request “show[ing] a sample of tallow produced by JBS contained 47 [ppb] of pentobarbital”; another set of tallow tests by UC Davis “show[ing] ... traces of pentobarbital from 16 ppb to 240 ppb, of which two ... were sent to [CPF]”; and additional correspondence between JBS and the Pennsylvania Department of Agriculture “detail[ing] at least two instances of JBS tallow ... containing between 620 and 680 ppb of pentobarbital.” (*Id.*, PageID.14446 ¶6(a).) Based on such reliable data, Dr. Callan concluded not only that pentobarbital was present in multiple lots of JBS tallow, including that purchased by CPF, but also that the wide variance in pentobarbital contamination, in his expert opinion, is indicative of the fact that “[t]he amount of pentobarbital varied widely from sample to sample.” (*Id.*, PageID.14447 ¶6(a)(iii).) Simply put, “[q]uantification of these results revealed a highly

heterogenous concentration of pentobarbital lot to lot, with results ranging from what UC Davis calls ‘trace’ hits (single digit part-per-billion) to 640 parts per billion or more.” (*Id.*, PageID.14446 ¶6(a).)

Furthermore, Dr. Callan testified that he had previously reviewed the FDA’s updated methodology for testing of pentobarbital in pet food, which specifically requires that pentobarbital is tested from a homogenized sample of beef tallow. (ECF No. 106-4, PageID.14556 (92:5-25).) That guidance provides that, “if the sample does not appear homogeneous, which is to say if sample appears heterogeneous, stir the 25 grams manually with a spatula or a spoon to ensure homogeneity.” (*Id.*, PageID.14557 (93:1-4).) The FDA’s warning against the use of heterogeneous samples of beef tallow when testing for pentobarbital supports that Dr. Callan’s concern over the impact of testing heterogeneous beef tallow samples for pentobarbital is neither speculative nor baseless.

Based on this reliable information, Dr. Callan opines that heterogeneity of beef tallow is a significant and relevant consideration because an uneven distribution of pentobarbital would further frustrate the ability to accurately estimate pentobarbital through sample testing of the Dog Food. (*Id.*, PageID.14485-86 (21:23-22:13).) Dr. Callan testified that representative testing using composite samples is not ideal for heterogeneous contaminants because mixing of multiple samples would “run the risk of even further diluting your sample and missing what

was there.” (*Id.*, PageID.14486 (22:9-13)); *see also* Ex. 3 at 171:3-7 (“[W]hen you’re working with something that is heterogonous in nature, you have to take care to make sure that the dispersion of that thing is uniform. Otherwise, your very small sample may totally miss an otherwise quantifiable or detectable amount of the substance in question.”). With this in mind, Dr. Callan concludes that the heterogeneous nature of pentobarbital distribution necessitates a larger sample size to accurately estimate the pentobarbital contamination. (ECF No. 106-4, PageID.14483 (19:14-19)); *see also* Ex. 3 at 171:9-15 (CPF “did not account for the fact that the sample in question may be variable in how much [pentobarbital] is present.”).

CPF criticizes Dr. Callan for not being familiar with certain granular details such as how JBS’s tallow is transported to CPF, how the tallow is stored, the temperature at which it is stored, how it is transported from the facilities to the truck and then to the next facilities. (ECF No. 106, PageID.14434-37); *see also* Ex. 3 at 190:22-191:17 (how CPF transported, unloaded, and used the tallow was irrelevant to his opinions because the contaminated tallow was not the result of a specific manufacturing process, so that he concluded it was unlikely that CPF “is transporting things in a way that is completely unique to the industry that would protect them in a way that it doesn’t protect anyone else.”). CPF offers no substantive evidence that these details are relevant when determining whether an ingredient is homogenous or

heterogeneous. CPF's argument that Dr. Callan did no personal testing of the lots is likewise unavailing because Dr. Callan may base his opinions on what he has been made aware of, as he has done here. Fed. R. Evid. 703; *Innovation Ventures*, 520 F. Supp. 3d at 892; *see also* Ex. 3 at 169:18-170:5 (Dr. Callan did not conduct his own testing because it was "beyond the necessity for the project at hand.... I don't need to perform testing in order to be able to make those deductions because the deductions, frankly, aren't analytical chemistry deductions. They're research methodology deductions."). And unlike the expert excluded in *Eiben v. Gorilla Ladder Company*, Dr. Callan's opinion is based on far more than speculation. No. 11-cv-10298, 2013 WL 1721677, at *15 (E.D. Mich. Apr. 22, 2013). His opinion is, instead, a scientific analysis of third party testing combined with an extensive understanding of statistics and data analysis and interpretation and expertise in chemistry technologies and environmental and industrial contaminants and toxins. There is no analytical gap, and his opinion is admissible.

IV. CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request this Court deny CPF's motion to exclude Dr. Callan.

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CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2022, I electronically filed the foregoing with the Clerk of the Court using the ECF system which will notify all counsel of record authorized to receive such filings.

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